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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,098	06/20/2001	Kenneth S. Koeneman	9426-022	2402

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PENNIE & EDMONDS LLP
1667 K STREET NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER
KELLY, ROBERT M

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,098	KOENEMAN ET AL.	
	Examiner	Art Unit	
	Robert M Kelly	1632	

-- Th MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a therapeutic agents comprising a bone sialoprotein promoter (BSP) and a protein-encoding sequence, classified in class 435, subclass 230.1.

II. Claims 13-14, drawn to a method of identification of compounds that modulate osteotropic gene expression, classified in class 435, subclass 4.

III. Claim 15, drawn to a pharmaceutical composition that modulates osteotropic gene expression, classified in class 514, subclass 1.

IV. Claims 16-28, drawn to methods of treating osteo-related disorders by administering a DNA encoding therapeutic proteins under the control of BSP regulatory sequences, classified in class 514, subclass 44.

V. Claims 29-30, drawn to methods of modulating immune functions comprising administering a DNA encoding a therpeutic sequence capable of modulating immune function under the control of a BSP, within a delivery vector, classified in class 435, subclass 69.3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are distinct inventions. The invention of Group I is directed to compositions comprising a BSP and a protein-encoding sequence. Further embodiments are directed to similar BSPs and protein-encoding sequences, further comprising either a prodrug or

a glucocorticoid or L-ascorbate. The invention of Group III is directed to modulators of osteo-tropic gene expression. Each of these compositions acts differently as a therapeutic agent. In the case of Group I, the vector encoding BSP and a protein-encoding sequence may be used to direct the expression of a gene. In the case of Group V, the therapeutic composition is a compound that alters gene expression of osteo-tropic proteins, and does not require the composition of Group I. In addition, it may exert its action by the regulation of genes already endogenously expressed. Therefore, the composition of Group V is patentably distinct from the invention of Group I.

Inventions II, IV, and V are distinct. The invention of Group II is directed to a method of identifying compounds that modulate osteotropic gene expression, the invention of Group IV is directed to methods of treating osteo-related disorders, and the invention of Group V is directed to the modulation of immune functions in an organism. The steps of the inventions of Groups II, VI, and V are not interchangeable. Moreover, the product of the method of Group II is a compound or set of compounds that regulate gene-expression, while the product of Group IV is the treatment of bone-related disorders, and the product of Group V is a modulated immune function. Also, the Groups II, IV, and V are classified differently. Therefore, the inventions of Groups IV and VI are distinct.

The compositions of the inventions of Groups I and III are distinct from the methods of the inventions of Groups II, IV, and V, although they may be related as product (Groups I and III) and process of using (Groups IV and V) or process of making (Group II with respect to Group III). In the of Groups IV and V, directed to methods of treating osteo-related disorders and methods of modulating immune function, any of the compositions may be applied in the use of the composition; however the product of Group I may be used in a materially-different

process (MPEP § 806.05(h)). Here, Group I may be used to express the encoded protein *in vitro*, screen for compounds that serve as prodrugs, or to up-regulate BSP expression. Also, the composition of Group III may be used for the up-regulation of BSP expression *in vitro*. In the case of Group II, directed to methods of screening for compounds, a similar argument may be made with regard to the inventions of Groups I and III, e.g., they may be used as therapeutic compositions for the treatment of disease in an organism. Furthermore, these compositions have other uses, e.g., as selection markers. Therefore, the inventions of Groups I and III are each patentably distinct from the inventions of Groups II, IV, and V.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art shown their classifications and their recognized divergent subject matter, and because each invention requires a separate non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently-named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b), and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention with respect to Group IV:

(a) growth factors;

(b) cytokines;

(c) therapeutic proteins;

(d) peptide hormones and fragments thereof;

(e) inhibitors of cytokines;

(f) peptide growth factors;

(g) peptide differentiation factors;

(h) interleukins;

(i) chemokines;

(j) interferons;

(k) colony stimulating factors; and

(l) angiogenic factors.

This application further contains claims directed to the following patentably distinct species of claimed invention with respect to Group V:

(a) interferon α;

(b) interferon β;

(c) interferon γ;

(d) tumor necrosis factor;

(e) granulocyte-macrophage colony-stimulating factor;

(f) macrophage colony stimulating factor;

(g) chemokines;

(h) macrophage chemoattractant and activating factor;

(i) RANTES;

(j) macrophage inflammatory peptides;

(k) complement;

(l) complement receptor ;

(m) accessory molecule 87.1;

(n) accessory molecule 87.2;

(o) ICAM-1.2;

(p) ICAM-1.3; and

(q) cytokine receptors.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 16-27 and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (703) 305-4460. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

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DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600